



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

NOV - 5 1998

9 3 4 3 '98 DEC -1 P1:49

Mr. John Morley  
Secretary  
Natural Factors Nutritional Products, Inc.  
1420 80th Street, S.W.  
Suite B  
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letters of October 20, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Natural Factors Nutritional Products, Inc. is making the following claims, among others, for the products:

**Dong Quai**

"...to mitigate menopause symptoms"

**Women's Vitex Extract**

"...maintain normal hormone levels in women experiencing premenstrual, menstrual and menopausal symptoms"

**Women's Black Cohosh Extract**

"...recognized for its ability to mitigate menopausal symptoms naturally"  
"...improved both physical and psychological symptoms in women experiencing menopause"

**Isoflavones Complex 50mg**

".....mitigate menopause symptoms without side effects"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease, namely,

975-0163

LET243

Page 2 - Mr. John Morley

disturbances associated with menopause. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

r/d:HFS-456:RMoore:11/3/98

f/t:HFS-456:rjm:11/3/98:docname:62048.adv:disc33



# Natural Factors Nutritional Products Inc.

October 20, 1998

Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C St. SW  
Washington, DC 20204

NOV - 2 1998

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Dong Quai

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonnevillle Pl.  
Burnaby, BC  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1420 80<sup>th</sup> St. SW, Suite B  
Everett, WA 98203

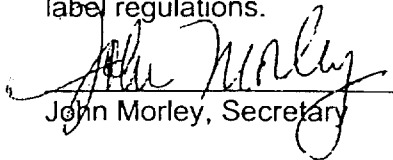
Text of the side panel: Dong Quai has been historically valued for over 2000 years in Asia. The precious phytochemicals in dong Quai tone and regulate the female reproductive system and are used to regulate menstruation and to mitigate menopause symptoms.\*

Text on PDP: Herbal Support for women's comfort\*

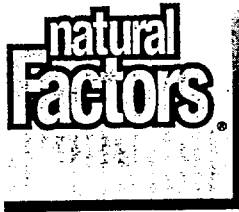
Name of dietary ingredient that is the subject of statement: Dong Quai

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

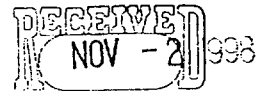
  
John Morley, Secretary

  
Date



# Natural Factors Nutritional Products Inc.

October 20, 1998



Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C St. SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement:	Women's Vitex Extract
Manufacturer, packer:	Natural Factors Nutritional Products, Ltd. 3655 Bonneville Pl. Burnaby, BC Canada V3N 4S9
Distributor:	Natural Factors Nutritional Products, Inc. 1420 80 <sup>th</sup> St. SW, Suite B Everett, WA 98203

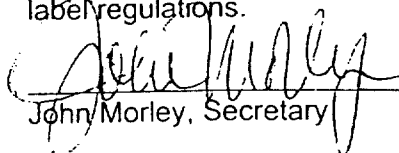
Text of the side panel: Natural Factors Vitex Extract capsules contain Vitex agnus-castus or "Vitex" extract standardized to 0.6% Aucubine. Revered by the ancient Greeks and widely prescribed by European gynecologists, this precious herb has been shown to maintain normal hormone levels in women experiencing premenstrual, menstrual and menopausal symptoms.


Text on PDP: Natural Support for Women's Hormones\*

Name of dietary ingredient that is the subject of statement: Vitex Extract

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, Secretary

  
Date



# Natural Factors Nutritional Products Inc.

October 20, 1998

Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C St. SW  
Washington, DC 20204

RECEIVED  
NOV - 2 1998

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Women's Black Cohosh Extract

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonneville Pl.  
Burnaby, BC  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1420 80<sup>th</sup> St. SW, Suite B  
Everett, WA 98203

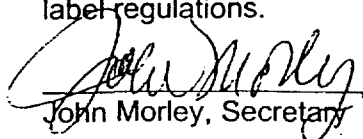
Text of the side panel: Natural Factors Black Cohosh Extract capsules contain extract standardized to 2.5% triterpene glycosides. This valuable phytoestrogen has been used for a number of feminine conditions and recently been recognized for its ability to mitigate menopause symptoms naturally. Recent studies show that Black Cohosh improved both physical and psychological symptoms in women experiencing menopause.\*

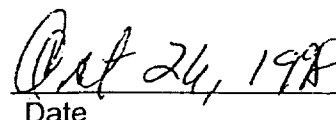
Text on PDP: Natural Support for Menopause Symptoms\*

Name of dietary ingredient that is the subject of statement: Black Cohosh

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, Secretary

  
Date



# Natural Factors Nutritional Products Inc.

October 20, 1998

RECEIVED  
NOV - 2 1998

Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C St. SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement:	Isoflavones Complex 50mg
Manufacturer, packer:	Natural Factors Nutritional Products, Ltd. 3655 Bonneville Pl. Burnaby, BC Canada V3N 4S9
Distributor:	Natural Factors Nutritional Products, Inc. 1420 80 <sup>th</sup> St. SW, Suite B Everett, WA 98203

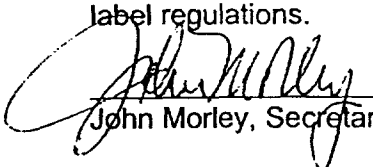
Text of the side panel: Natural Factors Isoflavones complex capsules contain naturally balanced isoflavones, including two major isoflavones genistein and daidzein. These two well-known flavonoids are complemented by other healthful natural compounds found in soybeans and soy foods. The precious phytoestrogens in soy are known to help maintain a healthy menstrual cycle and mitigate menopause symptoms without side effects.\*

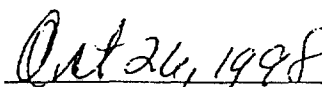
Text on PDP: Support to Balance the Effects of Estrogen\*

Name of dietary ingredient that is the subject of statement: Soy Isoflavones

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, Secretary

  
Date

1420 80th Street S.W., Suite B.  
Everett, WA, USA 98203  
PHONE (425) 513-8800  
FAX (425) 348-9050

62048